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FEB 2 5 1992

#13

Ronald L. Wilson, Director Health Assessment Policy Staff Office of Health Affairs (HFY-20) Food and Drug Administration 5600 Fisher's Lane, Room 11-44 Rockville, MD 20857

Dear Mr. Wilson:

The enclosed application for extension of the patent term of U.S. Patent No. 4,455,297 issued on June 19, 1984, was filed on February 14, 1992, under 35 USC § 156.

Your assistance is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC § 156 (g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is N0T to be considered as notice which may be made in the future pursuant to 35 USC § 156 (d) (2) (A).

Our review of the application to date indicates that the subject matter would be eligible for extension of the patent term under 35 USC § 156.

C. E. Vantton

Charles E. Van Horn

Patent Policy & Programs Administrator

Office of the Assistant Commissioner for Patents

cc: Douglas P. Mueller
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